Complete Summary

GUIDELINE TITLE

Type 1 diabetes in adults. National clinical guideline for diagnosis and management in primary and secondary care.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Chronic Conditions. Type 1 diabetes in adults. National clinical guideline for diagnosis and management in primary and secondary care. London (UK): Royal College of Physicians; 2004. 171 p. [382 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Type 1 diabetes mellitus and its complications and associated conditions, especially eye, kidney, and nerve damage and arterial disease affecting the heart, brain, and feet

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nephrology
Neurology
Nutrition
Ophthalmology
Podiatry
Psychology

INTENDED USERS

Advanced Practice Nurses
Dietitians
Health Care Providers
Hospitals
Nurses
Patients
Physicians
Podiatrists
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To offer the best practice advice on the care of adults (defined as those aged 18 years or older) with Type 1 diabetes
- To provide guidance on the management, monitoring, and support of people with Type 1 diabetes
- To help all healthcare professionals provide optimal services for people with Type 1 diabetes by:
    - Providing healthcare professionals with a set of explicit statements on the best known ways to assist people with diabetes with their most common clinical problems, while maximising the effectiveness of the service in supporting the population with Type 1 diabetes
    - Giving commissioning organisations and provider services specific guidance on the best way to provide complex services in a way that maximises efficiency and equity (service organisation is, however, outside the scope of this clinical guideline)
    - Informing people with diabetes of the optimal methods for helping them self-manage their diabetes

TARGET POPULATION

Adults (aged 18 years or older) with type 1 diabetes

The guideline did not cover:

- The management of women with diabetes who wish to conceive or who are pregnant
- The management of women who develop diabetes during pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Diagnostic laboratory glucose measurement/clinical monitoring of glucose
    - High-precision Diabetes Control and Complications Trial (DCCT)-aligned methods of haemoglobin A_{1c} (HbA_{1c})
2. HbA_{1c} levels
3. Measurement of auto-antibodies
4. Measurement of C-peptide
5. Testing for ketones
6. Self-monitoring of glucose
7. Assessment of self-management skills
8. Assessment of arterial risk factors annually including:
    - Albumin excretion rate
    - Smoking
    - Blood glucose control
    - Blood pressure
    - Full lipid profile (including high-density lipoprotein [HDL] and low-density lipoprotein [LDL] cholesterol and triglycerides)
    - Age
    - Family history of arterial disease
    - Abdominal adiposity
9. Annual structured eye surveillance including digital retinal photography and visual acuity testing
10. Annual urine albumin excretion/urine protein/serum creatinine
11. Annual inspection and examination of feet
12. Weight/body mass index
13. Psychological well-being

General Management Principles

1. Provision of open-access services
2. Provision of an individual care plan to be reviewed annually that includes the following:
    - Diabetes education including nutritional advice
    - Insulin therapy
    - Self monitoring
    - Arterial risk factor surveillance and management
    - Late complications surveillance and management
    - Provision of means and frequency of communication with the professional care team
    - Follow-up consultations including next annual review
3. Provision of a multidisciplinary team approach to in-patients with diabetes
4. Provision of information on diabetes support groups (local and national)
5. Provision of educational assessment and education input commensurate with the assessed risk of foot complications

6. Referral to a service offering medical and surgical management of erectile dysfunction

Pharmacological Treatments

1. Unmodified ("soluble") insulin
2. Rapid-acting insulin analogues
3. Isophane (NPH) insulin
4. Long-acting insulin analogues (insulin glargine)
5. Biphasic insulin preparations (pre-mixes)
6. Biphasic rapid-acting insulin analogue pre-mixes
7. Insulin pump therapy
8. Insulin lispro
9. Oral glucose-lowering drugs such as acarbose, sulfonylurea, and metformin (considered, but not recommended)
10. Glucose/sucrose-containing fluid
11. Glucose-containing tablets or gels
12. Intramuscular glucagons
13. Intravenous glucose
14. Aspirin therapy
15. Statin therapy
16. Fibrates or other lipid-lowering drugs
17. Beta-adrenergic blockers
18. Thiazide diuretic
19. Long-acting calcium channel antagonists
20. Angiotensin-converting enzyme (ACE) inhibitors
21. Angiotensin 2 receptor antagonists
22. Antibiotic therapy for foot ulcer
23. Phosphodiesterase-5 (PDE5) inhibitor
24. Metoclopramide
25. Domperidone
26. Cisapride
27. Simple analgesics (paracetamol, aspirin)
28. Tricyclic antidepressants
29. Gabapentin
30. Carbamazepine
31. Phenytoin
32. Opiate analgesia
33. Isotonic saline

Non-Pharmacological Treatments

1. Dietary interventions and management
2. Patient education techniques
3. Carer education techniques
4. Lifestyle management including physical activity, smoking cessation, and diet

MAJOR OUTCOMES CONSIDERED

- Accuracy of diagnostic tests
- Morbidity and mortality
- Metabolic outcomes

- Glycaemic control
- Risk for and incidence of diabetic complications
- Quality of life
- Quality-adjusted life years (QALYs)
- Patient satisfaction
- Cost measures including cost-effectiveness, cost-per-life year, and cost-per-quality-adjusted-life year
- Patient adherence

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searching for the evidence

There were four stages to evidence identification and retrieval:

1. The technical team set out a series of specific clinical questions (see Appendix A of the original guideline document) that covered the issues identified in the project scope. The consensus/reference group (CRG) met to discuss, refine, and approve these questions as suitable for identifying appropriate evidence from within the published literature.
2. A total of 74 questions were identified. The technical team and project executive agreed that a full literature search and critical appraisal process could not be undertaken for all of these areas due to the time limitations of the guideline development process. The technical team identified questions where it was felt that a full literature search and critical appraisal were essential. Reasons for this included an awareness of new or unclear evidence, or a particular clinical need for evidence-based guidance in the area.
3. The information scientist, with the assistance of the clinical advisor, developed a search strategy for each question to identify the available evidence. Identified titles and abstracts were reviewed for relevance to the agreed clinical questions and full papers obtained as appropriate. These were assessed for inclusion according to predefined criteria as developed by the Scottish Intercollegiate Guidelines Network (SIGN).
4. The full papers were critically appraised by the health services research fellow and the pertinent data entered into evidence tables. These were then reviewed and analysed by the guideline development group (GDG) as the basis upon which recommendations were formulated.

Due to the large amount of literature potentially relevant to Type 1 diabetes, the inclusion criteria aimed to limit the included studies to those of a higher level (see "Rating Scheme for the Strength of the Evidence" definitions below) conducted primarily in people with Type 1 diabetes. Where these were not available, lower-level studies, well-conducted studies outside Type 1 diabetes (in Type 2 diabetes

or in the non-diabetic population), or more methodologically-limited studies in people with Type 1 diabetes, were included.

Limited details of the databases and constraints used in the searches can be found in Appendix A of the original guideline document. No formal contact was made with the authors of identified studies. Additional contemporary articles identified by the GDG on an ad hoc basis, and further published evidence identified by national stakeholder organisations, were incorporated where appropriate after having been assessed for inclusion by the same criteria as evidence provided by the electronic searches.

Searches were rerun at the end of the guideline development process, thus including evidence published and included in the literature databases up to 27 May 2003. Studies recommended by stakeholders or GDG members that were published after this date were not considered for inclusion. The date should be the starting point for searching for new evidence for future updates to this guideline.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Hierarchy of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one controlled study without randomisation

IIb: Evidence obtained from at least one other type of quasi experimental study

III: Evidence obtained from non-experimental descriptive studies, such as comparative studies, correlation studies, and case control studies

IV: Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

DS: Evidence obtained from diagnostic studies

NICE: Evidence obtained from National Institute for Health and Clinical Excellence (NICE) guidelines or Health Technology Appraisal programme

METHODS USED TO ANALYZE THE EVIDENCE

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Synthesising the Evidence

Abstracts of articles identified by the searches were screened for relevance, and hard copies were ordered of papers that appeared to provide useful evidence relevant to each clinical question. Using a validated appraisal tool, each paper was assessed for its methodological quality against pre-defined criteria. Papers that met the inclusion criteria were then assigned a level according to the evidence hierarchy defined above (see "Rating Scheme for the Strength of the Evidence"). Owing to practical limitations, selection, critical appraisal, and data extraction were undertaken by one reviewer only. Evidence was, however, considered carefully by the guideline development group (GDG) for accuracy and completeness.

Each clinical question dictated the study design that was prioritised in the search strategy. In addition, certain topics within any one clinical question at times required different evidence types to be considered. Randomised control trials (RCTs) were the most appropriate study design for some clinical questions as they lend themselves particularly well to research into medicines. They were not, however, appropriate for all clinical questions, for example the evaluation of diagnostic tests.

RCTs are difficult to perform in areas such as rehabilitation and lifestyle, where interventions are often tailored to the needs of the individual. As a consequence, pharmaceutical interventions tend to be placed higher in the evidence hierarchy than other, equally important, interventions. This should not be interpreted as a preference for a particular type of intervention or as a reflection of the quality of the evidence, particularly for those clinical areas where non-RCT evidence is valid and most appropriate.

Where available, evidence from well-conducted systematic reviews was appraised and presented. Trials included within these reviews are listed in the evidence table but were not critically appraised. Studies identified in addition to those included in the systematic review were included in the appraisal process.

At times, evidence was not available from studies that included a Type 1 diabetes population. Where a Type 2 or mixed diabetes population, or non-diabetes population, is considered, it is indicated in the relevant evidence statement.

On occasion the group identified a clinical question that could not be appropriately answered through undertaking a rigorous literature review (because the evidence was scarce or conflicting). These questions were addressed by group consensus, and the group considered a summary of the area in an expert-drafted discussion paper. In these instances there was no formal assessment of the studies cited.

Finally, national and international evidence-based guidelines were referred to during the development process. These were not formally appraised because of

the consistency of process and of evidence base can be difficult to ascertain across such documents.

The evidence statements should be read with the following caveats in mind:

- All comparisons discussed are statistically significant unless otherwise stated.
- Where evidence is available from a good quality systematic review or meta-analysis, then individual studies are not reviewed and referenced. Any additional RCT evidence presented relates to studies published since the completion of systematic review(s) included or those considered relevant to this guideline, but which may not have been suitable for inclusion in the systematic review(s)
- Unless explicitly stated, all studies relate to diabetes populations. The inclusion of studies of Type 1, Type 2, or mixed Type 1 and Type 2 diabetes populations varies between questions (see Appendix A of the original guideline document)
- Descriptions of studies of poor methodological quality in evidence statements include details on all relevant interventions in a specified question. However, no positive recommendations have been based solely on such studies.
- Evidence statements in this guideline derived from one systematic review may be graded with different hierarchy of evidence in different places, due to some topics within the review being based on a synthesis of the outcomes of well-conducted RCTs and others being based on a synthesis of non-randomised studies, prevalence studies, and diagnostic studies, or on consensus
- When other guidelines are reviewed, some of their recommendations are presented here as evidence statements. These may not necessarily reflect the recommendations made in this guideline and are clearly labeled
- Where individual trials are referred to in the evidence statements as small, medium, or large, this equates to the following number of participants (at baseline): small, less than 50; medium, from 50 to 200; large, greater than 200. Exact numbers for each trial can be found in the online evidence tables.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Nominal Group Technique)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Developers

The National Collaborating Centre for Chronic Conditions (NCC-CC)

The NCC-CC is housed by the Royal College of Physicians (RCP) but governed by a multiprofessional partners board, which includes patient groups and National Health Service (NHS) management. It was set up in 2000 to undertake commissions from the National Institute for Health and Clinical Excellence (NICE) to develop clinical guidelines for the NHS in England and Wales.

The Technical Team

The technical team consisted of:

- An information scientist
- A health services research fellow
- A clinical advisor
- A health economist
- The chair of the Guideline Development Group (GDG)
- A project manager

and was supported by administrative personnel. It took part in the GDG meetings, and also met separately each month.

The GDG

The GDG met monthly for 10 months to review the evidence identified by the technical team, to comment on its completeness, and to develop and refine clinical recommendations based on that evidence and other considerations.

Editorial responsibility for this guideline rests solely with the GDG.

Nominations for group members were invited from various stakeholder organisations, which were selected to ensure an appropriate mix of clinical professions and patient groups. These made up the Consensus Reference Group (CRG, see below) and from their members the GDG was selected to represent the groups involved in the day-to-day management of Type 1 diabetes. It included two representatives of people with Type 1 diabetes. Each nominee was expected to serve as an individual expert in their own right and not as a mandated representative, although they were encouraged to keep their parent organisation informed of the process. Group membership details can be found at the front of the original guideline document.

The CRG

The larger CRG met twice during the process, once early in the development to ensure the aims and clinical questions (see Appendix A of the original guideline document) were appropriate, and again at the end of the process to review the validity of the recommendations drafted by the GDG. The formal consensus technique used for this purpose was developed by the NCC-CC and is a modification of the RAND Nominal Group Technique.

Involvement of People with Type 1 Diabetes

The NCC-CC believes that the views of people with diabetes and their carers are an integral part of the development process of a guideline on Type 1 diabetes. Patient organisation representation (Diabetes UK) was secured on the GDG and included a non-healthcare professional with Type 1 diabetes. People with diabetes were also present as part of the GDG and CRG and were involved at every stage of the guideline development process.

Drafting the Recommendations

Evidence for each topic was extracted into tables and summarised in evidence statements. The GDG reviewed the evidence tables and statements at each meeting and reached a group opinion. Recommendations were explicitly linked to the evidence supporting them and graded according to the level of evidence upon which they were based, using the grading system detailed in Section 2.6 of the original guideline document and in the section of this summary titled "Rating Scheme for the Strength of the Recommendations."

It should be noted that it is the level of evidence that determines the grade assigned to each recommendation. The grade does not necessarily reflect the clinical importance attached to the recommendation.

Agreeing Recommendations

Once the evidence review had been completed and an early draft of the guideline produced, a one-day meeting of the CRG was held to finalise the recommendations. This included a pre-meeting vote on the recommendations and a further vote at the CRG meeting, where the group was asked to consider the draft guideline in two stages:

1. Are the evidence-based statements acceptable and is the evidence cited sufficient to justify the grading attached?
2. Are the recommendations derived from the evidence justified and are they sufficiently practical so that those at the clinical front line can implement them? Three types of recommendation were considered:
    a. A recommendation from the GDG based on strong evidence, usually non-controversial unless there was important evidence that had been missed or misinterpreted
    b. A recommendation that was based on good evidence but where it was necessary to extrapolate the findings to make it useful in the National Health Service. The extrapolation was approved by consensus
    c. Recommendations for which no evidence existed but which address important aspects of care, and for which a consensus on best practice could be reached.

This formal consensus method has been established within the NCC-CC, drawing on the knowledge set out in a health technology appraisal, the work of the Royal College of Nursing Institute and practical experience. It approximates to a modification of the RAND Nominal Group Technique and will be fully described in future publications.

Writing the Guideline

The draft version of the guideline was drawn up by the technical team in accordance with the decisions of the guideline groups.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations

A: Based on category I evidence

B: Based on category II evidence or extrapolated from category I

C: Based on category III evidence or extrapolated from category I or II

D: Directly based on category IV evidence or extrapolated from category I, II or III

COST ANALYSIS

Health Economic Evidence

While evidence on cost-effectiveness was extracted from the clinical literature searches wherever it existed, this was rare. As such, a separate search was conducted to isolate the health economic evidence that attempted to identify the cost of, and the benefits accruing from, each strategy or intervention. An a priori study design criterion was not imposed, so information may come from sources other than randomised controlled trials (RCTs) and formal economic evaluations.

As the management of diabetes is complex, many of the areas covered by this guideline have little economic evidence; within clinical trials it is not always clear which of a range of interventions and strategies actually improves health. The Guideline Development Group (GDG) therefore expected the useful cost-effectiveness evidence to fall within a limited range of areas. Where searching produced either no evidence or insufficient evidence for a substantive health economic evidence statement, this fact is indicated.

The health economist presented the economic evidence to the GDG alongside the clinical evidence. There is no standard measure to assess the quality of the economic evidence, and reported costs and benefits experienced in other healthcare systems may not apply in the UK. The GDG had to assess not only the results but also their applicability.

Health economic analysis can provide a framework for combining information from a variety of sources to form a standard comparison of cost and benefits. However, the task of producing these estimates is complex and labour intensive, and requires a level of clinical evidence that is not always readily available. Evidence on the costs and benefits of a broad range of interventions was presented to the GDG, but the issue of cultured human dermis for foot ulceration was identified as a particularly important area for further economic analysis. The choice was made on the grounds that:

- This treatment does not have good quality economic evidence attached.
- It has a potentially large health benefit.
- If made available, the treatment could have a large effect on National Health Service (NHS) resources given the prevalence of diabetic foot ulcers.
- There are uncertainties surrounding both the benefits and resources, and an absence of cost-utility studies.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

1. The first draft of the guideline (the full guideline, National Institute for Health and Clinical Excellence [NICE] guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG)
2. The final consultation draft of the Full guideline, the NICE guideline, and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Evidence categories (Ia–IV) and recommendation grades (A–D) are defined at the end of the "Major Recommendations" field.

In addition to evidence-based recommendations, the guideline development group (GDG) also identifies evidence from diagnostic studies (DS) and from the National Institute for Health and Clinical Excellence (NICE) guidelines or health technology appraisal programme (NICE).

Diagnosis

D - Diabetes should be confirmed by a single diagnostic laboratory glucose measurement in the presence of classical symptoms, or by a further laboratory glucose measurement. The diagnosis may be supported by a raised haemoglobin A_{1c} (HbA_{1c}).

D - Where diabetes is diagnosed, but Type 2 diabetes suspected, the diagnosis of Type 1 diabetes should be considered if:

- ketonuria is detected, or
- weight loss is marked, or
- the person does not have features of the metabolic syndrome or other contributing illness

D - When diabetes is diagnosed in a younger person, the possibility that the diabetes is not Type 1 diabetes should be considered if they are obese or have a family history of diabetes, particularly if they are of non-white ethnicity.

D - Tests to detect specific auto-antibodies or to measure C-peptide deficiency should not be regularly used to confirm the diagnosis of Type 1 diabetes. Their

use should be considered if predicting the rate of decline of islet B-cell function would be useful in discriminating Type 1 from Type 2 diabetes.

Care Process and Support

Optimal Healthcare Processes

D - Advice to adults with Type 1 diabetes should be provided by a range of professionals with skills in diabetes care working together in a coordinated approach. A common environment (diabetes centre) is an important resource in allowing a diabetes multidisciplinary team to work and communicate efficiently while providing consistent advice.

C - Open-access services should be provided on a walk-in and telephone-request basis during working hours to adults with Type 1 diabetes, and a helpline staffed by people with specific diabetes expertise should be provided on a 24-hour basis. Adults with diabetes should be provided with contact information for these services.

D - An individual care plan should be set up and reviewed annually, modified according to changes in wishes, circumstances, and medical findings, and the details recorded. The plan should include aspects of:

- Diabetes education including nutritional advice (see sections below titled "Education Programmes for Adults with Type 1 Diabetes" and "Dietary Management")
- Insulin therapy (see sections below titled "Insulin Regimens" and "Insulin Delivery")
- Self-monitoring (see section below titled "Self-Monitoring of Blood Glucose")
- Arterial risk factor surveillance and management (see section below titled "Arterial Risk Control")
- Late complications surveillance and management (see sections below on late complications)
- Means and frequency of communication with the professional care team
- Follow-up consultations including next annual review

D - Population, practice-based, and clinic diabetes registers (as specified by the National Service Framework) should be used to assist programmed recall for annual review and assessment of complications and vascular risk.

A - Conventional technology (telephones), or newer technologies for high-density data transmission of images, should be used to improve process and outcomes.

D - The multidisciplinary team approach should be available to inpatients with diabetes, regardless of the reason for admission (see section titled "Inpatient Management).

Support Groups

C - At the time of diagnosis and periodically thereafter, adults with diabetes should be offered up-to-date information on the existence of and means of

contacting diabetes support groups (local and national), and the benefits of membership.

Education, Programmes and Self-Care

Education Programmes for Adults with Type 1 Diabetes

Specific recommendations on patient education and information-giving in particular aspects of care are given in individual sections of this guideline.

A - A programme of structured diabetes education covering all major aspects of diabetes self-care and the reasons for it should be made available to all adults with Type 1 diabetes in the months after diagnosis, and periodically thereafter according to agreed need following yearly assessment.

D - Education programmes for adults with Type 1 diabetes should be flexible so that they can be adapted to specific educational, social, and cultural needs. These needs should be integrated with individual health needs as dictated by the impact of diabetes and other relevant health conditions on the individual.

D - Education programmes for adults with Type 1 diabetes should be designed and delivered by members of the multidisciplinary diabetes team in accordance with the principles of adult education.

D - Education programmes for adults with Type 1 diabetes should include modules designed to empower adults to participate in their own healthcare through:

- Enabling them to make judgments and choices about how they effect that care
- Obtaining appropriate input from the professionals available to advise them.

D - Professionals engaged in the delivery of diabetes care should consider incorporating educational interchange at all opportunities when in contact with a person with Type 1 diabetes. The professional should have the skills and training to make best use of such time.

D - More formal review of self-care and needs should be made annually in all adults with Type 1 diabetes, and the agenda addressed each year should vary according to the priorities agreed between the healthcare professional and the person with Type 1 diabetes.

Self-Monitoring of Blood Glucose

D - Self-monitoring of blood glucose levels should be used as part of an integrated package that includes appropriate insulin regimens and education to help choice and achievement of optimal diabetes outcomes.

D - Self-monitoring skills should be taught close to the time of diagnosis and initiation of insulin therapy.

D - Self-monitoring results should be interpreted in the light of clinically significant life events.

D - Self monitoring should be performed using meters and strips chosen by adults with diabetes to suit their needs, and usually with low blood requirements, fast analysis times, and integral memories.

D - Structured assessment of self-monitoring skills, the quality and use made of the results obtained, and the equipment used should be made annually. Self-monitoring skills should be reviewed as part of annual review, or more frequently according to need, and reinforced where appropriate.

D - Adults with Type 1 diabetes should be advised that the optimal frequency of self monitoring will depend on:

- The characteristics of an individual's blood glucose control
- The insulin treatment regimen
- Personal preference in using the results to achieve the desired lifestyle

D - Adults with Type 1 diabetes should be advised that the optimal targets for short-term glycaemic control are:

- A pre-prandial blood glucose level of 4.0 to 7.0 mmol/L and
- A post-prandial blood glucose level of less than 9.0 mmol/L

Note: These values are different than those given in the recommendations for children and young people with Type 1 diabetes because of clinical differences between these two age groups.

D - Monitoring using sites other than the fingertips (often the forearm, using meters that require small volumes of blood and devices to obtain those small volumes) cannot be recommended as a routine alternative to conventional self-blood glucose monitoring.

Dietary Management

D - Nutritional information sensitive to personal needs and culture should be offered from the time of diagnosis of Type 1 diabetes.

D - Nutritional information should be offered individually and as part of a diabetes education programme (see education recommendations above). Information should include advice from professionals with specific and approved training and continuing accredited education in delivering nutritional advice to people with health conditions. Opportunities to receive nutritional advice should be offered at intervals agreed between adults with Type 1 diabetes and their advising professionals.

A - The hyperglycaemic effects of different foods a person with Type 1 diabetes wishes to eat should be discussed in the context of the insulin preparations chosen to match those food choices.

A - Programmes should be available to adults with Type 1 diabetes to enable them to make:

- Optimal choices about the variety of foods they wish to consume
- Insulin dose changes appropriate to reduce glucose excursions when taking different quantities of those foods

D - The choice of content, timing, and amount of snacks between meals or at bedtime available to the person with Type 1 diabetes should be agreed on the basis of informed discussion about the extent and duration of the effects of consumption of different food types and the insulin preparations available to match them. Those choices should be modified on the basis of discussion of the results of self-monitoring tests.

D - Information should also be made available on:

- Effects of different alcohol-containing drinks on blood glucose excursions and calorie intake
- Use of high-calorie and high-sugar "treats"
- Use of foods of high glycaemic index

D - Information about the benefits of healthy eating in reducing arterial risk should be made available as part of dietary education in the period after diagnosis, and according to need and interest at intervals thereafter. This should include information about low glycaemic index foods, fruit and vegetables, and types and amounts of fat, and ways of making the appropriate nutritional changes.

D - Nutritional recommendations to individuals should be modified to take account of associated features of diabetes, including:

- Excess weight and obesity
- Underweight
- Eating disorders
- Raised blood pressure
- Renal failure

D - All healthcare professionals providing advice on the management of Type 1 diabetes should be aware of appropriate nutritional advice on common topics of concern and interest to adults living with Type 1 diabetes, and should be prepared to seek advice from colleagues with more specialised knowledge. Suggested common topics include:

- Glycaemic index of specific foods
- Body weight, energy balance, and obesity management
- Cultural and religious diets, feasts, and fasts
- Foods sold as "diabetic"
- Sweeteners
- Dietary fibre intake
- Protein intake
- Vitamin and mineral supplements

- Alcohol
- Matching carbohydrate, insulin, and physical activity
- Salt intake in hypertension
- Comorbidities including nephropathy and renal failure, coeliac disease, cystic fibrosis, or eating disorders
- Use of peer support groups

Physical Activity

C - Adults with Type 1 diabetes should be advised that physical activity can reduce their enhanced arterial risk in the medium and longer term.

D - Adults with Type 1 diabetes who choose to integrate increased physical activity into a more healthy lifestyle should be offered information about:

- Appropriate intensity and frequency of physical activity
- Role of self-monitoring of changed insulin and/or nutritional needs
- Effect of activity on blood glucose levels (likely fall) when insulin levels are adequate
- Effect of exercise on blood glucose levels when hyperglycaemic and hypoinsulinaemic (risk of worsening of hyperglycaemia and ketonaemia)
- Appropriate adjustments of insulin dosage and/or nutritional intake for exercise and post-exercise periods, and the next 24 hours
- Interactions of exercise and alcohol
- Further contacts and sources of information

Cultural and Individual Lifestyle

D - Each adult with Type 1 diabetes should be managed as an individual, rather than as a member of any cultural, economic, or health-affected group. Attention should be paid to the recommendations given elsewhere in this guideline with respect to the cultural preferences of individual adults with Type 1 diabetes.

Blood Glucose Control and Insulin Therapy

Clinical Monitoring of Blood Glucose

D - Clinical monitoring of blood glucose levels by high-precision Diabetes Control and Complications Trial (DCCT)-aligned methods of HbA1c should be performed every two to six months, depending on:

- Achieved level of blood glucose control
- Stability of blood glucose control
- Change in insulin dose or regimen

D - Site-of-care measurement or measurement before clinical consultation should be provided.

D - HbA_{1c} results should be communicated to the person with Type 1 diabetes after each measurement. The term "A1c" can be used for simplicity.

A - Total glycated haemoglobin (GHb) estimation or assessment of glucose profiles should be used where haemoglobinopathy or haemoglobin turnover invalidate HbA_{1c} measurement.

B - Fructosamine should not be used as a routine substitute for HbA_{1c} estimation.

B - Continuous glucose monitoring systems have a role in the assessment of glucose profiles in adults with consistent glucose control problems on insulin therapy, notably:

- Repeated hyper- or hypoglycaemia at the same time of day
- Hypoglycaemia unawareness, unresponsive to conventional insulin dose adjustment

Glucose Control Assessment Levels

B - Adults with Type 1 diabetes should be advised that maintaining a DCCT-harmonised HbA_{1c} below 7.5% is likely to minimise their risk of developing diabetic eye, kidney, or nerve damage in the longer term.

D - Adults with Type 1 diabetes who want to achieve an HbA_{1c} down to, or towards, 7.5% should be given all appropriate support in their efforts to do so.

NICE - Where there is evidence of increased arterial risk (identified by a raised albumin excretion rate, features of the metabolic syndrome, or other arterial risk factors), people with Type 1 diabetes should be advised that approaching lower HbA_{1c} levels (for example, 6.5% or lower) may be of benefit to them. Support should be given to approaching this target if so wished.

B - Where target HbA_{1c} levels are not reached in the individual, adults with Type 1 diabetes should be advised that any improvement is beneficial in the medium and long term, and that greater improvements towards the target level lead to greater absolute gains.

D - Undetected hypoglycaemia and an attendant risk of unexpected disabling hypoglycaemia or of hypoglycaemia unawareness should be suspected in adults with Type 1 diabetes who have:

- Lower HbA_{1c} levels, in particular levels in or approaching the normal reference range (DCCT harmonised <6.1%)
- HbA_{1c} levels lower than expected from self-monitoring results

D - Where experience or risk of hypoglycaemia is significant to an individual, or the effort needed to achieve target levels severely curtails other quality of life despite optimal use of current diabetes technologies, tighter blood glucose control should not be pursued without balanced discussion of the advantages and disadvantages.

Note: A new chemical standard for HbA_{1c} has been developed by the International Federation of Clinical Chemistry (IFCC). This reads lower by around 2.0% (units), and will be the basis of primary calibration of instruments from 2004 onwards.

However, this does not preclude the use of DCCT-harmonised levels, and views from patient organisations and professional bodies at a recent Department of Health meeting (July 2003) are that all HbA_{1c} reports should be DCCT aligned, pending some internationally concerted policy change.

Insulin Regimens

A - Adults with Type 1 diabetes should have access to the types (preparation and species) of insulin they find allow them optimal well-being.

D - Cultural preferences need to be discussed and respected in agreeing the insulin regimen for a person with Type 1 diabetes.

A - Multiple insulin injection regimens, in adults who prefer them, should be used as part of an integrated package of which education, food, and skills training should be integral parts.

D - Appropriate self-monitoring and education should be used as part of an integrated package to help achieve optimal diabetes outcomes.

D - Meal-time insulin injections should be provided by injection of unmodified ("soluble") insulin or rapid-acting insulin analogues before main meals.

A - Rapid-acting insulin analogues should be used as an alternative to meal-time unmodified insulin:

- Where nocturnal or late inter-prandial hypoglycaemia is a problem
- In those in whom they allow equivalent blood glucose control without use of snacks between meals and this is needed or desired

D - Basal insulin supply (including nocturnal insulin supply) should be provided by the use of isophane (NPH) insulin or long-acting insulin analogues (insulin glargine). Isophane (NPH) insulin should be given at bedtime. If rapid-acting insulin analogues are given at meal times or the midday insulin dose is small or lacking, the need to give isophane (NPH) insulin twice daily (or more often) should be considered.

D - Long-acting insulin analogues (insulin glargine) should be used when:

- Nocturnal hypoglycaemia is a problem on isophane (NPH) insulin
- Morning hyperglycaemia on isophane (NPH) insulin results in difficult daytime blood glucose control
- Rapid-acting insulin analogues are used for meal-time blood glucose control

D - Twice-daily insulin regimens should be used by those adults who consider number of daily injections an important issue in quality of life.

- Biphasic insulin preparations (pre-mixes) are often the preparations of choice in this circumstance.
- Biphasic rapid-acting insulin analogue pre-mixes may give an advantage to those prone to hypoglycaemia at night.

Such twice daily regimens may also help:

- Those who find adherence to their agreed lunch-time insulin injection difficult
- Adults with learning difficulties who may require assistance from others

D - Adults whose nutritional and physical activity patterns vary considerably from day to day, for vocational or recreational reasons, may need careful and detailed review of their self-monitoring and insulin injection regimen(s). This should include all the appropriate preparations (see recommendations above regarding use of rapid-acting insulin analogues, isophane [NPH] insulin, and long-acting insulin analogues [insulin glargine]) and consideration of unusual patterns and combinations.

D - For adults undergoing periods of fasting or sleep following eating (such as during religious feasts and fasts or after night-shift work), a rapid-acting insulin analogue before the meal (provided the meal is not prolonged) should be considered.

D - For adults with erratic and unpredictable blood glucose control (hyper- and hypoglycaemia at no consistent times), rather than a change in a previously optimised insulin regimen, the following should be considered:

- Resuspension of insulin and injection technique
- Injection sites
- Self-monitoring skills
- Knowledge and self-management skills
- Nature of lifestyle
- Psychological and psychosocial difficulties
- Possible organic causes such as gastroparesis

NICE - Continuous subcutaneous insulin infusion (or insulin pump therapy) is recommended as an option for people with Type 1 diabetes provided that:

- Multiple-dose insulin therapy (including, where appropriate, the use of insulin glargine) has failed;* and
- Those receiving the treatment have the commitment and competence to use the therapy effectively.

*Note: People for whom multiple-dose therapy has failed are considered to be those for whom it has been impossible to maintain an HbA_{1c} level no greater than 7.5% (or 6.5% in the presence of microalbuminuria or adverse features of the metabolic syndrome) without disabling hypoglycaemia occurring, despite a high level of self care of their diabetes. "Disabling hypoglycaemia," for the purpose of this guidance, means the repeated and unpredicted occurrence of hypoglycaemia requiring third-party assistance that results in continuing anxiety about recurrence and is associated with significant adverse effect on quality of life.

D - Partial insulin replacement to achieve blood glucose control targets (basal insulin only, or just some meal-time insulin) should be considered for adults starting insulin therapy, until such time as islet B-cell deficiency progresses further.

D - Clear guidelines and protocols ("sick-day rules") should be given to all adults with Type 1 diabetes to assist them in adjusting insulin doses appropriately during intercurrent illness.

D - Oral glucose-lowering drugs should generally not be used in the management of adults with Type 1 diabetes.

Insulin Delivery

D - Adults with Type 1 diabetes who inject insulin should have access to the insulin injection delivery device they find allows them optimal well-being, often using one or more types of insulin injection pen.

D - Adults with Type 1 diabetes who have special visual or psychological needs should be provided with injection devices or needle-free systems that they can use independently for accurate dosing.

D - Insulin injection should be made into the deep subcutaneous fat. To achieve this, needles of a length appropriate to the individual should be made available.

D - Adults with Type 1 diabetes should be informed that the abdominal wall is the therapeutic choice for mealtime insulin injections.

D - Adults with Type 1 diabetes should be informed that extended-acting suspension insulin (for example isophane [NPH] insulin) may give a longer profile of action when injected into the subcutaneous tissue of the thigh rather than the arm or abdominal wall.

D - Adults with Type 1 diabetes should be recommended to use one anatomical area for the injections given at the same time of day, but to move the precise injection site around in the whole of the available skin within that area.

D - Adults with Type 1 diabetes should be provided with suitable containers for the collection of used needles. Arrangements should be available for the suitable disposal of these containers.

D - Injection site condition should be checked annually, and if new problems with blood glucose control occur.

Hypoglycaemia: Prevention of Hypoglycaemia, Problems Related to Hypoglycaemia, and Management of Symptomatic Hypoglycaemia

A - Adults with Type 1 diabetes should be informed that any available glucose/sucrose-containing fluid is suitable for the management of hypoglycaemic symptoms or signs in people who are able to swallow. Glucose-containing tablets or gels are also suitable for those able to dissolve or disperse these in the mouth and swallow the products.

D - When a more rapid-acting form of glucose is required, purer glucose-containing solutions should be given.

D - Adults with decreased level of consciousness due to hypoglycaemia who are unable to take oral treatment safely should be:

- Given intramuscular glucagon by a trained user (intravenous glucose may be used by professionals skilled in obtaining intravenous access)
- Monitored for response at 10 minutes, and then given intravenous glucose if the level of consciousness is not improving significantly
- Then given oral carbohydrate when it is safe to administer it, and placed under continued observation by a third party who has been warned of the risk of relapse

B - Adults with Type 1 diabetes should be informed that some hypoglycaemic episodes are an inevitable consequence of insulin therapy in most people using any insulin regimen, and that it is advisable that they should use a regimen that avoids or reduces the frequency of hypoglycaemic episodes while maintaining as optimal a level of blood glucose control as is feasible. Advice to assist in obtaining the best such balance from any insulin regimen should be available to all adults with Type 1 diabetes. (See sections above titled "Insulin regimens" and "Insulin delivery").

D - When hypoglycaemia becomes unusually problematic or of increased frequency, review should be made of the following possibly contributory causes:

- Inappropriate insulin regimens (incorrect dose distributions and insulin types)
- Meal and activity patterns, including alcohol
- Injection technique and skills, including insulin resuspension
- Injection site problems
- Possible organic causes including gastroparesis
- Changes in insulin sensitivity (the latter including drugs affecting the renin-angiotensin system and renal failure)
- Psychological problems
- Previous physical activity
- Lack of appropriate knowledge and skills for self management

D - Hypoglycaemia unawareness should be assumed to be secondary to undetected periods of hypoglycaemia (<3.5 mmol/litre, often for extended periods, commonly at night) until these are excluded by appropriate monitoring techniques. If present, such periods of hypoglycaemia should be ameliorated.

D - Specific education on the detection and management of hypoglycaemia in adults with problems of hypoglycaemia awareness should be offered.

D - Nocturnal hypoglycaemia (symptomatic or detected on monitoring) should be managed by:

- Reviewing knowledge and self-management skills
- Reviewing current insulin regimen and evening eating habits and previous physical activity
- Choosing an insulin type and regimen with less propensity to induce low glucose levels in the night hours, such as:
    - Isophane (NPH) insulin at bedtime
    - Rapid-acting analogue with the evening meal

- Long-acting insulin analogues (insulin glargine)
- Insulin pump

D - Adults with Type 1 diabetes should be informed that late post-prandial hypoglycaemia may be managed by appropriate inter-prandial snacks or the use of rapid-acting insulin analogues before meals.

D - Where early cognitive decline occurs in adults on long-term insulin therapy, normal investigations should be supplemented by the consideration or investigation of possible brain damage due to overt or covert hypoglycaemia, and the need to ameliorate this.

Arterial Risk Control

Identification of Arterial Risk

C - Arterial risk factors should be assessed annually, and the assessment should include:

- Albumin excretion rate
- Smoking
- Blood glucose control
- Blood pressure
- Full lipid profile (including high-density lipoprotein [HDL] and low-density lipoprotein [LDL] cholesterol and triglycerides)
- Age
- Family history of arterial disease (CVD)
- Abdominal adiposity

DS - Arterial risk tables, equations, or engines for calculation of arterial risk should not be used because they underestimate risk in adults with Type 1 diabetes.

D - Adults with raised albumin excretion rate (microalbuminuria), or two or more features of the metabolic syndrome (see table below) should be managed as the highest risk category (as though they had Type 2 diabetes or declared arterial disease).

Table: Features of the Metabolic Syndrome Suggesting High Arterial Risk in Adults with Type 1 Diabetes

Feature	Women	Men
Blood pressure average (mmHg)	>135/80	>135/80
Waist circumference (m) - Use 0.1 m lower figures for people of South Asian extraction	>0.90	>1.00
Serum HDL cholesterol (mmol/L)	<1.2	<1.0
Serum triglycerides (mmol/L)	>1.8	>1.8

Table Notes:

- Raised albumin excretion rate is not included, because in Type 1 diabetes it is a marker of developing nephropathy, and nephropathy alone is associated with extreme risk of ischaemic heart disease.
- Glucose intolerance cannot be assessed in adults with Type 1 diabetes, but higher insulin doses in adults >20 years (>1.0 U/kg/day) suggest insulin insensitivity.

D - Adults with Type 1 diabetes who are not in the highest risk category but who have other arterial risk factors (increasing age over 35 years, family history of premature heart disease, of ethnic group with high risk, or with more severe abnormalities of blood lipids or blood pressure) should be managed as a moderately-high-risk group.

D - Where there is no evidence of additional arterial risk, the management of lipids and blood pressure should follow normal procedures for the non-diabetes population, using appropriate clinical guidelines.

Interventions to Reduce Risk and to Manage Arterial Disease

These recommendations assume that arterial risk has been assessed according to the recommendations in the section above titled "Identification of Arterial Risk." Blood glucose control, blood pressure control, and education programmes for adults with Type 1 diabetes are considered elsewhere in this guideline.

D - Adults with Type 1 diabetes who smoke should be given advice on smoking cessation and use of smoking cessation services, including NICE guidance-recommended therapies. The messages should be reinforced in continuing smokers yearly if pre-contemplative of stopping, and at all clinical contacts if there is a prospect of their stopping.

D - Young adult non-smokers should be advised never to start smoking.

B - Aspirin therapy (75 mg daily) should be recommended in adults in the highest and moderately-high risk categories.

B - A standard dose of a statin should be recommended for adults in the highest risk and moderately-high risk groups. Therapy should not be stopped if alanine aminotransferase (ALT) is raised to less than three times the upper limit of reference range.

D - If several statins are not tolerated, fibrates and other lipid-lowering drugs should be considered as indicated according to assessed arterial disease risk status.

D - Fibrates should be recommended for adults with hypertriglyceridaemia according to local lipid-lowering guidelines and arterial disease risk status.

D - Responses to therapy should be monitored by assessment of lipid profile. If the response is unsatisfactory, the following causes should be considered: non-concordance, inappropriate drug choice, and the need for combination therapy.

D - Adults who have had myocardial infarction or stroke should be managed intensively, according to relevant non-diabetes guidelines. In the presence of angina or other ischaemic heart disease, beta-adrenergic blockers should be considered. (For use of insulin in these circumstances, see section below titled "Inpatient Management").

Blood Pressure

D - Intervention levels for recommending blood pressure management should be 135/85 mmHg unless the person with Type 1 diabetes has abnormal albumin excretion rate or two or more features of the metabolic syndrome (see Table above), in which case it should be 130/80 mmHg. See also the recommendation regarding blood pressure treatment in the section below titled "Kidney Damage."

D - To allow informed choice by the person with the condition, the following should be discussed:

- Reasons for choice of intervention level
- Substantial potential gains from small improvements in blood pressure control
- Possible negative consequences of therapy

See also the recommendation regarding blood pressure treatment in the section below titled "Kidney Damage."

D - A trial of a low-dose thiazide diuretic should be started as first-line therapy for raised blood pressure, unless the person with Type 1 diabetes is already taking a renin-angiotensin system blocking drug for nephropathy (see the section below titled "Kidney Damage"). Multiple drug therapy will often be required.

D - Adults with Type 1 diabetes should be offered information on the potential for lifestyle changes to improve blood pressure control and associated outcomes, and offered assistance in achieving their aims in this area.

D - Concerns over potential side effects should not be allowed to inhibit advising and offering the necessary use of any class of drugs, unless the side effects become symptomatic or otherwise clinically significant. In particular:

- Selective beta-adrenergic blockers should not be avoided in adults on insulin.
- Low-dose thiazides may be combined with beta-blockers.
- When calcium channel antagonists are prescribed, only long-acting preparations should be used.
- Direct questioning should be used to detect the potential side effects of erectile dysfunction, lethargy, and orthostatic hypotension with different drug classes.

Management of Late Complications: Diabetic Eye Disease

Retinopathy Surveillance Programmes

A - Eye surveillance for adults newly diagnosed with Type 1 diabetes should be started from diagnosis.

B - Depending on the findings, structured eye surveillance should be followed by:

- Routine review in one year, or
- Earlier review, or
- Referral to an ophthalmologist

A - Structured eye surveillance should be at one-year intervals.

C - The reasons and success of eye surveillance systems should be properly conveyed to adults with Type 1 diabetes, so that attendance is not reduced by ignorance of need or fear of outcome.

Screening Tests for Retinopathy

B - Digital retinal photography should be implemented for eye surveillance programmes for adults with Type 1 diabetes.

B - Mydriasis with tropicamide should be used when photographing the retina, D - after prior agreement with the person with Type 1 diabetes following discussion of the advantages and disadvantages, including appropriate precautions for driving.

D - Visual acuity testing should be a routine part of eye surveillance programmes.

Referral

D - Emergency review by an ophthalmologist should occur for:

- Sudden loss of vision
- Rubeosis iridis
- Pre-retinal or vitreous haemorrhage
- Retinal detachment

D - Rapid review by an ophthalmologist should occur for new vessel formation.

D - Referral to an ophthalmologist should occur for:

- Referable maculopathy:
    - Exudate or retinal thickening within one disc diameter of the centre of the fovea
    - Circinate or group of exudates within the macula (the macula is defined here as a circle centred on the fovea, of a diameter the distance between the temporal border of the optic disc and the fovea)
    - Any microaneurysm or haemorrhage within one disc diameter of the centre of the fovea, only if associated with a best visual acuity of 6/12 or worse
- Referable pre-proliferative retinopathy:
    - Any venous beading
    - Any venous loop or reduplication
    - Any intraretinal microvascular abnormalities (IRMA)
    - Multiple deep, round or blot haemorrhages

- Any unexplained drop in visual acuity

Management of Late Complications: Diabetic Kidney Disease

Kidney Damage

See also recommendations for "blood pressure" above.

D - All adults with Type 1 diabetes with or without detected nephropathy should be asked to bring in a first-pass morning urine specimen once a year. This should be sent for estimation of albumin:creatinine ratio. Estimation of urine albumin concentration alone is a poor alternative. Serum creatinine should be measured at the same time.

DS - If an abnormal surveillance result is obtained (in the absence of proteinuria/urinary tract infection) the test should be repeated at each clinic visit or at least every three to four months, and the result taken as confirmed if a further specimen (out of two more) is also abnormal (>2.5 mg/mmol for men, >3.5 mg/mmol for women).

DS - Other renal disease should be suspected:

- In the absence of progressive retinopathy
- If blood pressure is particularly high
- If proteinuria develops suddenly
- If significant haematuria is present
- In the presence of systemic ill health

D - The significance of a finding of abnormal albumin excretion rate should be discussed with the person concerned.

A - Angiotensin-converting enzyme (ACE) inhibitors should be started and (with the usual precautions) titrated to full dose in all adults with confirmed nephropathy (including those with microalbuminuria alone) and Type 1 diabetes.

B - If ACE inhibitors are not tolerated, angiotensin 2 receptor antagonists should be substituted. Combination therapy is not recommended at present.

D - Blood pressure should be maintained below 130/80 mmHg by addition of other anti-hypertensive drugs if necessary.

B - Adults with Type 1 diabetes and nephropathy should be advised about the advantages of not following a high protein diet.

D - Referral criteria for tertiary care should be agreed between local diabetes specialists and nephrologists.

Management of Late Complications: Diabetes Foot Problems

Screening and Surveillance of Diabetic Foot Problems

D - Structured foot surveillance should be at one-year intervals, and should include educational assessment and education input commensurate with the assessed risk.

D - The reasons for and success of foot surveillance systems should be properly conveyed to adults with Type 1 diabetes, so that attendance is not reduced by ignorance of need.

D - Inspection and examination of feet should include:

- Skin condition
- Shape and deformity
- Shoes
- Impaired sensory nerve function
- Vascular supply (including peripheral pulses)

DS - Use of a 10-g monofilament plus non-traumatic pin prick is advised for detection of impairment of sensory nerve function sufficient to significantly raise risk of foot ulceration.

Management of Foot Ulceration and Associated Risk Factors

Foot Complication Surveillance

D - On the basis of findings from foot care surveillance, foot ulceration risk should be categorised into:

- Low current risk (normal sensation and palpable pulses)
- Increased risk (impaired sensory nerve function or absent pulses, or other risk factor)
- High risk (impaired sensory nerve function and absent pulses or deformity or skin changes, or previous ulcer)
- Ulcer present

Foot Care Management

B - For people found to be at increased risk or high risk of foot complications:

- Arrange specific assessment of other contributory risk factors including deformity, smoking, and level of blood glucose control.
- Arrange/reinforce specific foot care education, and review those at high risk as part of a formal foot ulcer prevention programme.
- Consider the provision of special footwear, including insoles and orthoses, if there is a deformity, callosities or previous ulcer.

B - For people with an ulcerated foot:

- Arrange referral to a specialist diabetes foot care team incorporating specifically trained foot care specialists (usually state-registered podiatrists) within one to two days if there is no overt infection of the ulcer or surrounding tissues, or as an emergency if such infection is present.

- Use antibiotics if there is any evidence of infection of the ulcer or surrounding tissues and continue these long term if infection is recurrent.
- Use foot dressings, taking account of cost according to local experience, ensuring arrangements are in place to monitor and change dressings frequently (often daily) accordingly to need.
- Remove dead tissue from diabetic foot ulcers.
- Consider the use of off-loading techniques (such as contact casting) for people with neuropathic foot ulcers.
- Do not use cultured human dermis (or equivalent), hyperbaric oxygen therapy, topical ketanserin, or growth factors in routine foot ulcer management.
- Consider ensuring complete and effective foot education through the use of graphic visualisations of the consequences of ill-managed foot ulceration in people with recurrent ulceration or previous amputation.
- Review progress in ulcer healing frequently (daily to monthly) according to need.
- If peripheral vascular disease is detected, refer for early assessment by a specialist vascular team.

Charcot Osteoarthropathy

D - Adults with suspected or diagnosed Charcot osteoarthropathy should be referred immediately to a multidisciplinary diabetes foot care team.

Management of Late Complications: Diabetes Nerve Damage

Diagnosis and Management of Erectile Dysfunction

D - Men should be asked annually whether erectile dysfunction is an issue.

A - A phosphodiesterase-5 (PDE5) inhibitor drug, if not contraindicated, should be offered where erectile dysfunction is a problem.

D - Referral to a service offering other medical and surgical management of erectile dysfunction should be discussed where phosphodiesterase-5 inhibitors are not successful.

Diagnosis and Management of Autonomic Neuropathy

D - In adults with Type 1 diabetes on insulin therapy who have erratic blood glucose control (or unexplained bloating or vomiting), the diagnosis of gastroparesis should be considered.

D - In adults with Type 1 diabetes who have altered perception of hypoglycaemia the possibility of sympathetic nervous system damage as a contributory factor should be considered.

D - In adults with Type 1 diabetes who have unexplained diarrhoea, particularly at night, the possibility of autonomic neuropathy affecting the gut should be considered.

D - Care should be taken when prescribing antihypertensive drugs not to expose people to the risks of orthostatic hypotension as a result of the combined effects of sympathetic autonomic neuropathy and blood pressure lowering drugs.

D - Adults with Type 1 diabetes who have bladder emptying problems should be investigated for the possibility of autonomic neuropathy affecting the bladder, unless other explanations are adequate.

D - The management of the symptoms of autonomic neuropathy should include standard interventions for the manifestations encountered (for example, for erectile dysfunction or abnormal sweating).

D - For adults with Type 1 diabetes with diagnosed or suspected gastroparesis a trial of prokinetic drugs is indicated (metoclopramide or domperidone, with cisapride* as third line if necessary).

*Note: Cisapride is not currently licensed in the United Kingdom (UK).

Anaesthesia Autonomic Neuropathy

D - Anaesthetists should be aware of the possibility of parasympathetic autonomic neuropathy affecting the heart in adults with diabetes who are listed for procedures under general anaesthetic and who have evidence of somatic neuropathy or other manifestations of autonomic neuropathy.

Optimum Management of Painful Neuropathy

D - Use of simple analgesics (paracetamol, aspirin) and local measures (bed cradles) are recommended as a first step, but if trials of these measures are ineffective, they should be discontinued and other measures should be tried.

A - Where initial measures fail, a low to medium dose of a tricyclic drug* should be used, timed to be taken before the time of day the symptoms are troublesome; adults with Type 1 diabetes should be advised that this is a trial of therapy.

*Note: Tricyclic antidepressants and carbamazepine are not currently licensed in the UK for painful neuropathy associated with Type 1 diabetes.

A - Where an adequate trial of tricyclic drugs* fails, a trial of gabapentin should be started and not stopped unless ineffective at the maximum tolerated dose or at least 1,800 mg per day.

*Note: Tricyclic antidepressants and carbamazepine are not currently licensed in the UK for painful neuropathy associated with Type 1 diabetes.

D - If treatment with gabapentin is unsuccessful, carbamazepine* and phenytoin* should be considered.

*Note: Tricyclic antidepressants and carbamazepine are not currently licensed in the UK for painful neuropathy associated with Type 1 diabetes. Phenytoin is currently licensed in the UK for neuropathic pain under specialist supervision.

D - Where severe chronic pain persists despite trials of other measures, opiate analgesia may be considered. At this stage the assistance of the local chronic pain management service should be sought.

D - Professionals should be alert to the psychological consequences of chronic painful neuropathy and offer appropriate management where they are identified.

D - Where drug therapy is successful in alleviating symptoms, trials of reduced dosage and cessation of therapy should be considered after six months of treatment.

D - Where neuropathic symptoms cannot be adequately controlled it is useful, to help individuals cope, to explain:

- The reasons for the problem
- The likelihood of remission in the medium term
- The role of improved blood glucose control

Management of Special Situations

Adults who Are Newly Diagnosed

D - At the time of diagnosis (or if necessary after the management of critically decompensated metabolism) the professional team should develop with and explain to the person with Type 1 diabetes a plan for their early care. To agree such a plan will generally require:

- Medical assessment to:
    - Ensure security of diagnosis of type of diabetes
    - Ensure appropriate acute care is given when needed
    - Review and detect potentially confounding disease and drugs
    - Detect adverse vascular risk factors
- Environmental assessment to understand:
    - Social, home, work, and recreational circumstances of the individual and carers
    - Their preferences in nutrition and physical activity
    - Other relevant factors such as substance use
- Cultural and educational assessment to identify prior knowledge and to enable optimal advice and planning about:
    - Treatment modalities
    - Diabetes education programmes
- Assessment of emotional state to determine the appropriate pace of education

The results of the assessment should be used to agree a future care plan.

Some items of the initial diabetes assessment:

- Acute medical history
- Social, cultural, and educational history/lifestyle review
- Complications history/symptoms

- Long-term/recent diabetes history
- Other medical history/systems
- Family history of diabetes/arterial disease
- Drug history/current drugs
- Vascular risk factors
- Smoking
- General examination
- Weight/body mass index
- Foot/eye/vision examination
- Urine albumin excretion/urine protein/serum creatinine
- Psychological well-being
- Attitudes to medicine and self-care
- Immediate family and social relationships and availability of informal support

D - Elements of an individualised and culturally appropriate plan will include:

- Sites and timescales of diabetes education including nutritional advice (see sections above titled "Education Programmes for Adults with Type 1 Diabetes" and "Dietary Management")
- Initial treatment modalities (see sections above titled "Insulin Regimens" and "Insulin Delivery")
- Means of self-monitoring (see section above titled "Self-Monitoring of Blood Glucose")
- Means and frequency of communication with the professional team
- Follow-up consultations including surveillance at annual review (see individual late complications recommendations)
- Management of arterial risk factors (see section above titled "Arterial Risk Control")

D - After the initial plan is agreed, arrangements should be put in place to implement it without inappropriate delay and to provide for feedback and modification of the plan over the ensuing weeks.

Diabetic Ketoacidosis (DKA)

D - Professionals managing DKA should be adequately trained including regular updating, and be familiar with all aspects of its management which are associated with mortality and morbidity. These topics should include:

- Fluid balance
- Acidosis
- Cerebral oedema
- Electrolyte imbalance
- Disturbed interpretation of familiar diagnostic tests (white cell count, body temperature, electrocardiography [ECG])
- Respiratory distress syndrome
- Cardiac abnormalities
- Precipitating causes
- Infection management including opportunistic infections
- Gastroparesis
- Use of high dependency and intensive care units
- And the recommendations below

Management of DKA should be in line with local clinical governance.

D - Primary fluid replacement in DKA should be with isotonic saline, not given too rapidly except in cases of circulatory collapse.

A - Bicarbonate should not generally be used in the management of DKA.

A - Intravenous insulin should be given by infusion in cases of DKA.

D - In the management of DKA, once plasma glucose concentration has fallen to 10 to 15 mmol/L, glucose-containing fluids should be given (not more than two litres in 24 hours) in combination with higher rates of insulin infusion than used in other situations (for example, 6 U/hour monitored for effect).

D - Potassium replacement should begin early in DKA, with frequent monitoring for the development of hypokalaemia.

A - Phosphate replacement should not generally be used in the management of DKA.

D - In patients whose conscious level is impaired, consideration should be given to insertion of a nasogastric tube, urinary catheterisation to monitor urine production, and heparinisation.

D - To reduce the risk of catastrophic outcomes in DKA, monitoring should be continuous and review should cover all aspects of clinical management at frequent intervals.

Inpatient Management

B - From the time of admission, the person with Type 1 diabetes and the team caring for him or her should receive, on a continuing basis, advice from a trained multidisciplinary team with expertise in diabetes.

D - Throughout the course of an inpatient admission, the personal expertise of adults with Type 1 diabetes (in managing their own diabetes) should be respected and routinely integrated into ward-based blood glucose monitoring and insulin delivery, using the person with Type 1 diabetes' own system. This should be incorporated into the nursing care plan.

D - Throughout the course of an inpatient admission, the personal knowledge and needs of adults with Type 1 diabetes regarding their dietary requirements should be a major determinant of the food choices offered to them (except when illness or medical or surgical intervention significantly disturbs those requirements).

D - Hospitals should ensure the existence and deployment of an approved protocol for inpatient procedures and surgical operations for adults with Type 1 diabetes. This should aim to ensure the maintenance of near-normoglycaemia without risk of acute decompensation, usually by the use of regular quality assured blood glucose testing driving the adjustment of intravenous insulin delivery.

D - Members of care teams managing adults with Type 1 diabetes in institutions, such as nursing homes, residential homes, and prisons, should follow the recommendations in this section.

Management During Acute Arterial Events

D - Optimal insulin therapy, which can be achieved by the use of intravenous insulin and glucose, should be provided to all adults with Type 1 diabetes with threatened or actual myocardial infarction or stroke. Critical care and emergency departments should have a protocol for such management.

Associated Disorders

DS - In adults with Type 1 diabetes who have a low body mass index or unexplained weight loss, markers of coeliac disease should be assessed.

D - Healthcare professionals should be alert to the possibility of the development of other autoimmune disease in adults with Type 1 diabetes (including Addison's disease, pernicious anaemia, and thyroid disorders).

Psychological Problems

B - Members of professional teams providing care or advice to adults with Type 1 diabetes should be alert to the development or presence of clinical or sub-clinical depression and/or anxiety, in particular where someone reports or appears to be having difficulties with self-management.

D - Diabetes professionals should ensure that they have appropriate skills in the detection and basic management of non-severe psychological disorders in people from different cultural backgrounds. They should be familiar with appropriate counselling techniques and appropriate drug therapy, while arranging prompt referral to specialists of those people in whom psychological difficulties continue to interfere significantly with well-being or diabetes self-management.

D - Special management techniques or treatment for non-severe psychological illness should not commonly be used, except where diabetes-related arterial complications give rise to special precautions over drug therapy.

Eating Disorders

C - Members of multidisciplinary professional teams should be alert to the possibility of bulimia nervosa, anorexia nervosa, and insulin dose manipulation in adults with Type 1 diabetes with:

- Over-concern with body shape and weight
- Low body mass index
- Poor overall blood glucose control

D - The risk of morbidity from the complications of poor metabolic control suggests that consideration should be given to early (and occasionally urgent) referral of adults with Type 1 diabetes to local eating disorder services.

D - Provision for high-quality professional team support at regular intervals with regard to counselling about lifestyle issues and particularly nutritional behaviour should be made for all adults with Type 1 diabetes from the time of diagnosis (see sections above titled "Education Programmes for Adults with Type 1 Diabetes" and "Dietary Management"). Refer to section 4 of the original guideline document for "Research recommendations."

Definitions:

Hierarchy of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one controlled study without randomisation

IIb: Evidence obtained from at least one other type of quasi experimental study

III: Evidence obtained from non-experimental descriptive studies, such as comparative studies, correlation studies, and case control studies

IV: Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

DS: Evidence obtained from diagnostic studies

NICE: Evidence obtained from National Institute for Health and Clinical Excellence (NICE) guidelines or Health Technology Appraisal programme

Grading of Recommendations

A: Based on category I evidence

B: Based on category II evidence or extrapolated from category I

C: Based on category III evidence or extrapolated from category I or II

D: Directly based on category IV evidence or extrapolated from category I, II or III

DS: Evidence from diagnostic studies

NICE: Evidence obtained from National Institute for Health and Clinical Excellence (NICE) guidelines or Health Technology Appraisal programme

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the key components of care of adults with Type 1 diabetes after diagnosis and at the annual and other regular reviews.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Good blood glucose and blood pressure control are known to prevent or delay the long-term complications of diabetes.

POTENTIAL HARMS

Adverse effects of insulin therapy, including hypoglycaemia and injection site reactions

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgment. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- The recommendations in the guideline are subject to a number of limitations. The sponsoring authority, the National Institute for Health and Clinical Excellence (NICE), is primarily concerned with health services in England and Wales, so the guideline only indirectly refers to:
    - Social services
    - The voluntary sector
    - Employers
    - Services supplied by secondary and tertiary specialties for the late complications of diabetes (for example renal, cardiological, urological and opthalmological services)
    - The education sector (including schools and universities)
    - Others concerned with an individual's health, rather than healthcare.

  Nonetheless, the importance of other agencies must not be ignored, and in each locality the aim should be to integrate care for people with Type 1 diabetes across all relevant sectors.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation in the National Health Service

Local health communities should review their existing practice for type 1 diabetes against this guideline. The review should consider the resources required to implement the recommendations, the people and processes involved, and the timeline over which full implementation is envisaged. It is in the interests of people with type 1 diabetes that the implementation timeline is as rapid as possible.

Relevant local clinical guidelines, care pathways, and protocols should be reviewed in the light of this guidance and revised accordingly.

This guideline should be used in conjunction with the National Service Framework for Diabetes (available from www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Diabetes/fs/en).

Key Priorities for Implementation.

Patient-Centred Care

- The views and preferences of individuals with Type 1 diabetes should be integrated into their healthcare. Diabetes services should be organised, and staff trained, to allow and encourage this.

Multidisciplinary Team Approach

- The range of professional skills needed for delivery of optimal advice to adults with diabetes should be provided by a multidisciplinary team. Such a team should include members having specific training and interest to cover the following areas of care:
    - Education/information giving
    - Nutrition
    - Therapeutics
    - Identification and management of complications
    - Foot care
    - Counselling
    - Psychological care

Patient Education

- Culturally appropriate education should be offered after diagnosis to all adults with Type 1 diabetes (and to those with significant input into the diabetes care of others). It should be repeated as requested and according to annual review of need. This should encompass the necessary understanding, motivation, and skills to manage appropriately:
    - Blood glucose control (insulin, self-monitoring, nutrition)
    - Arterial risk factors (blood lipids, blood pressure, smoking)

- Late complications (feet, kidney, eye, heart)

Blood Glucose Control

- Blood glucose control should be optimised towards attaining Diabetes Control and Complications Trial (DCCT)-harmonised haemoglobin A_{1c} (HbA_{1c}) targets for prevention of microvascular disease (7.5% or lower) and, in those at increased risk, arterial disease (6.5% or lower) as appropriate, while taking into account:
  - The experiences and preferences of the insulin user, in order to avoid hypoglycaemia
  - The necessity to seek advice from professionals knowledgeable of the range of available mealtime and basal insulins and of optimal combinations thereof, and their optimal use.

Arterial Risk Factor Control

- Adults with Type 1 diabetes should be assessed for arterial risk at annual intervals. Those found to be at increased risk should be managed through appropriate interventions and regular review. Note should be taken of:
  - Microalbuminuria, in particular
  - The presence of features of the metabolic syndrome
  - Conventional risk factors (family history, abnormal lipid profile, raised blood pressure, smoking)

Late Complications

Adults with Type 1 diabetes should be assessed for early markers and features of eye, kidney, nerve, foot, and arterial damage at annual intervals. According to assessed need, they should be offered appropriate interventions and/or referral in order to reduce the progression of such late complications into adverse health outcomes affecting quality of life.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Chronic Conditions. Type 1 diabetes in adults. National clinical guideline for diagnosis and management in primary and secondary care. London (UK): Royal College of Physicians; 2004. 171 p. [382 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Chronic Conditions - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Group (GDG)
Consensus Reference Group (CRG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Consensus Reference Group (CRG)

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All group members made a formal "declaration of interests" at the start of the guideline development and provided updates throughout. The National

Collaborating Centre for Chronic Conditions (NCC-CC) and the Guideline Development Group (GDG) Chair monitored these.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format [PDF] format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- National Collaborating Centre for Women's and Children's Health and the National Collaborating Centre for Chronic Conditions. Type 1 diabetes: diagnosis and management of type 1 diabetes in children, young people and adults. London (UK): National Institute for Clinical Excellence (NICE); 2004 Jul. 112 p. (Clinical guideline; no. 15). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Type 1 diabetes: diagnosis and management of type 1 diabetes in adults. Quick reference guide. National Collaborating Centre for Chronic Conditions, 2004 Jul. 14 p. Available from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref: N0558. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Section 3.3 of the original guideline document.

PATIENT RESOURCES

The following is available:

- Type 1 diabetes in adults. Understanding NICE guidance – information for adults with type 1 diabetes, their families and carers, and the public. National Institute for Clinical Excellence (NICE), 2004 Jul. 64 p. Available from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref N0559. 11 Strand, London, WC2N 5HR.

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NGC STATUS

This NGC summary was completed by ECRI on March 4, 2005. The information was verified by the guideline developer on September 29, 2006.

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